UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **August 31, 2015**

TREVENA, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-36193	**26-1469215**
(Commission File No.)	(IRS Employer Identification No.)

1018 West 8th Avenue, Suite A
King of Prussia, PA 19406
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: **(610) 354-8840**

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 Regulation FD.

In connection with its press release dated August 31, 2015, Trevena, Inc. (the "Company") will hold a conference call and webcast on August 31, 2015. Details regarding accessing the conference call and webcast are contained in the press release under the heading "Conference Call and Webcast." A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference. The information contained in the press release furnished as Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and is not incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

Item 8.01 Other Events.

On August 31, 2015, the Company announced results from its randomized, double-blind, placebo- and active-controlled Phase 2b trial of TRV130 in moderate to severe postoperative pain after abdominoplasty surgery. The trial achieved its primary endpoint of statistically greater pain reduction than placebo over 24 hours. In addition, TRV130 was superior to morphine in pre-specified secondary measures, exhibiting significantly reduced nausea, vomiting, and hypoventilation events. In the trial, two regimens of TRV130 were tested: the first consisted of a 1.5 mg intravenous loading dose with 0.1 mg self-administered on-demand doses as often as every 6 minutes (together referred to here as "TRV130 0.1 mg") using a patient controlled analgesia (PCA) device; the second consisted of a 1.5 mg loading dose with 0.35 mg on-demand doses (together referred to here as "TRV130 0.35 mg") using a PCA device. A commonly used morphine PCA regimen was also tested, consisting of a 4 mg loading dose with 1 mg on-demand doses. Placebo was administered as a loading dose and on-demand doses that were volume-matched to the active regimens. Specifically, the Company reported the following results:

Efficacy

- TRV130 demonstrated statistically significant pain reduction compared to placebo and comparable efficacy to morphine. The TRV130 0.1 mg regimen reduced average pain scores (LS mean change in time-weighted average over 24 hours) by 2.3 points ($p<0.0001$ vs. placebo). The TRV130 0.35 mg regimen reduced average pain scores by 2.1 points ($p=0.0003$ vs. placebo), similar to morphine, which reduced average pain scores by 2.1 points ($p=0.0001$ vs. placebo).
- TRV130 provided rapid reduction in average pain scores, consistent with the previous Phase 2 trial where TRV130 showed more rapid onset of meaningful pain relief than morphine.
- Rescue analgesic use was similar for both TRV130 and morphine, and less than half the rate of rescue analgesic use for placebo. The proportion of patients using rescue analgesic was 64% with placebo, 31% with TRV130 0.1 mg, 21% with TRV130 0.35 mg, and 25% with morphine (post hoc $p<0.0005$ for all three active arms vs. placebo).

Safety and tolerability

- In this study, the TRV130 groups had a significantly lower prevalence (percentage of patients) of hypoventilation events (a measure of respiratory safety), nausea, and vomiting than the morphine group (post hoc $p<0.05$ for both TRV130 regimens vs. morphine).

	Placebo	TRV130 0.1 mg	TRV130 0.35 mg	Morphine
Hypoventilation	10%	15%	31%	53%
Vomiting	8%	15%	15%	42%
Nausea	18%	41%	46%	72%

- Adverse events associated with TRV130 were largely opioid-related; the most frequently reported events were nausea, vomiting, hypoventilation and headache. Opioid-related AEs were generally less frequent in the TRV130 groups compared to morphine. No drug-related serious adverse events were reported in the study.

Total TRV130 use in the study was similar for the two TRV130 regimens with mean cumulative doses of 7.6 mg and 5.4 mg for the TRV130 0.1 mg and TRV130 0.35 mg regimens, respectively. The mean cumulative dose of morphine was 26.3 mg.

The Phase 2b study was a randomized, double-blind, placebo- and active-controlled, multiple dose, adaptive study in 200 patients undergoing abdominoplasty surgery at a single center in the United States. At baseline, patients had a mean baseline pain score on the numerical pain rating scale (NPRS) of 7.7 out of 10, which is considered severe pain. Pain intensity was measured using validated numeric rating scales at multiple time points up to 24 hours

All study arms used a flexible dose, PCA administration regimen intended to optimize treatment and reflect the as-needed dosing most commonly used with post-operative opioid analgesics. All regimens were blinded and volume-matched, and consisted of intravenous loading doses followed by patient-controlled intravenous doses with a 6 minute lockout period after every on-demand dose. Patients were assigned randomly to post-operative regimens of TRV130, placebo, or morphine, in a 2:1:2 ratio respectively, beginning when post-operative pain became moderate or severe in intensity and continuing for 24 hours thereafter.

Rescue analgesics were available as necessary for patients whose pain was not adequately treated by TRV130, morphine, or placebo; first line rescue was oral ibuprofen and second line rescue was oral oxycodone. A standard methodology was used to avoid including effects of rescue analgesics on pain intensity measures: an unscheduled pain intensity assessment was made before rescue analgesic dosing, and this value was used instead of the scheduled pain intensity values until the end of the study.

In this trial, respiratory safety was measured as hypoventilation events, defined as clinically apparent and persistently decreased respiratory rate, respiratory effort or oxygen saturation. In practice, such events can result in interruption of opioid analgesic administration or, if unrecognized and if additional opioids are administered, to more serious consequences.

A pre-specified interim analysis was conducted after enrollment of 100 patients to evaluate opportunities for studying additional regimens of TRV130, after which the on-demand dose of TRV130 was increased to 0.35 mg for the remaining portion of the study.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Number	Description
99.1	Press release dated August 31, 2015

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TREVENA, INC.

Date: August 31, 2015

By: /s/ John M. Limongelli
John M. Limongelli
Sr. Vice President, General Counsel & Corporate Secretary

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release dated August 31, 2015.

Trevena Announces Positive Results from Phase 2b Study of TRV130 in Acute Postoperative Pain

— Novel mu-opioid receptor modulator TRV130 achieved primary endpoint —
— Superior safety and tolerability profile of TRV130 compared to morphine —
— Company to host conference call at 5:00 PM EDT —

KING OF PRUSSIA, PA, August 31, 2015 — Trevena, Inc. (NASDAQ: TRVN), a clinical stage pharmaceutical company focused on the discovery and development of biased ligands targeting G protein coupled receptors (GPCRs), today announced positive data from its randomized, double-blind, placebo- and active-controlled Phase 2b trial of TRV130 in moderate to severe acute postoperative pain after abdominoplasty surgery. The study achieved its primary endpoint of statistically greater pain reduction than placebo over 24 hours. In addition, TRV130 was superior to morphine in pre-specified secondary measures, exhibiting significantly reduced nausea, vomiting, and hypoventilation events.

"The data from this trial showed that TRV130, when given on-demand, matched morphine efficacy for pain relief with a markedly improved safety and tolerability profile," said Neil Singla, M.D., chief scientific officer of Lotus Clinical Research and lead investigator of the study. "The challenges of safely and adequately titrating morphine are well recognized, and these data suggest that, if approved, TRV130 may provide a better option than currently available opioid analgesics."

In the trial, two regimens of TRV130 were tested: the first consisted of a 1.5 mg intravenous loading dose with 0.1 mg self-administered on-demand doses as often as every 6 minutes (together referred to here as "TRV130 0.1 mg") using a patient controlled analgesia (PCA) device; the second consisted of a 1.5 mg loading dose with 0.35 mg on-demand doses (together referred to here as "TRV130 0.35 mg") using a PCA device. A commonly used morphine PCA regimen was also tested, consisting of a 4 mg loading dose with 1 mg on-demand doses. Placebo was administered as a loading dose and on-demand doses that were volume-matched to the active regimens.

Study Results

Efficacy

- TRV130 demonstrated statistically significant pain reduction compared to placebo and comparable efficacy to morphine. The TRV130 0.1 mg regimen reduced average pain scores (LS mean change in time-weighted average over 24 hours) by 2.3 points ($p<0.0001$ vs. placebo). The TRV130 0.35 mg regimen reduced average pain scores by 2.1 points ($p=0.0003$ vs. placebo), similar to morphine, which reduced average pain scores by 2.1 points ($p=0.0001$ vs. placebo).
- TRV130 provided rapid reduction in average pain scores, consistent with the previous Phase 2 trial where TRV130 showed more rapid onset of meaningful pain relief than morphine.
- Rescue analgesic use was similar for both TRV130 and morphine, and less than half the rate of rescue analgesic use for placebo. The proportion of patients using rescue analgesic was 64% with placebo, 31% with TRV130 0.1 mg, 21% with TRV130 0.35 mg, and 25% with morphine (post hoc $p<0.0005$ for all three active arms vs. placebo).

Safety and tolerability

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	Placebo	TRV130 0.1 mg	TRV130 0.35 mg	Morphine
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Total TRV130 use in the study was similar for the two TRV130 regimens with mean cumulative doses of 7.6 mg and 5.4 mg for the TRV130 0.1 mg and TRV130 0.35 mg regimens, respectively. The mean cumulative dose of morphine was 26.3 mg.

Full results will be presented at a future scientific conference or in a journal publication.

"The positive data from this study continue the impressive accumulation of evidence suggesting meaningful differentiation of TRV130 from morphine," said Maxine Gowen, Ph.D., chief executive officer of Trevena. "The goal of new analgesic drug discovery has long been the provision of more powerful pain relief with reduced opioid-related adverse effects. We believe the Trevena biased ligand platform has delivered this profile in TRV130 and we look forward to starting Phase 3 development in early 2016."

Study Design

The Phase 2b study was a randomized, double-blind, placebo- and active-controlled, multiple dose, adaptive study in 200 patients undergoing abdominoplasty surgery at a single center in the United States. At baseline, patients had a mean baseline pain score on the numerical pain rating scale (NPRS) of 7.7 out of 10, which is considered severe pain. Pain intensity was measured using validated numeric rating scales at multiple time points up to 24 hours

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A pre-specified interim analysis was conducted after enrollment of 100 patients to evaluate opportunities for studying additional regimens of TRV130, after which the on-demand dose of TRV130 was increased to 0.35 mg for the remaining portion of the study.

Conference Call and Webcast

Date:	Monday, August 31, 2015
Time:	5:00 p.m. (EDT)
Telephone Access:	(855) 465-0180
International:	(484) 756-4313
Conference ID:	26412950

To access the live audio webcast of the presentation and the slides, please visit the Investor Presentation section of the Company's website. The webcast will be available for replay for 7 days.

About moderate-to-severe acute pain

Mu opioid receptor agonists such as morphine and fentanyl are the most effective class of analgesics currently available and are the standard of care in postoperative pain; however, in published national surveys, a significant proportion of surgical patients have reported inadequate pain relief despite use of opioid analgesics. Opioid-related adverse effects such as respiratory depression, nausea and vomiting, are frequently dose-limiting, which complicates pain management and increases the burden of care.

About TRV130

TRV130 was designed to optimize opioid receptor pharmacology to deliver an improved analgesic profile. TRV130 is a biased mu opioid receptor ligand which in preclinical studies activated analgesic signals while avoiding signals that can interfere with analgesia and promote respiratory depression and gastrointestinal dysfunction. In late 2014, the Company reported data from a Phase 2a/b trial comparing TRV130 to placebo and morphine following bunionectomy surgery. In this trial, TRV130 3 mg demonstrated superior efficacy to a standard dose of morphine, with average reduction in numeric pain rating scale up to 6 points from a baseline of 7 points. This efficacy was achieved without any serious adverse events and without significant respiratory depression as measured by oxygen desaturation. A previous study in healthy volunteers showed that TRV130, in a series of experimental models, elicited analgesia superior to that of morphine with less respiratory depression and vomiting and lower severity of nausea. Trevena believes that TRV130 may have an improved profile compared to currently used opioid analgesics and could offer enhanced pain relief with a reduced burden of opioid-related adverse events. Trevena anticipates that the initial market opportunity for TRV130, if approved, will be in the acute care settings, with a focus on postoperative pain in the hospital.

About Trevena

Trevena, Inc. is a clinical stage biopharmaceutical company that discovers, develops and intends to commercialize therapeutics that use a novel approach to target G protein coupled receptors, or GPCRs. Using its proprietary product platform, Trevena is developing four biased ligand product candidates it has identified — TRV027 to treat acute heart failure (Phase 2b), TRV130 to treat moderate to severe acute pain intravenously (completed Phase 2), TRV734 to treat moderate to severe acute and chronic pain orally (Phase 1), and TRV250 for treatment-refractory migraine and other CNS disorders (preclinical).

Cautionary Note on Forward Looking Statements

Any statements in this press release about future expectations, plans and prospects for the company, including statements about the company's strategy, future operations, clinical development of its therapeutic candidates, plans for potential future product candidates and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "suggest," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the status, timing, costs, results and interpretation of the company's clinical trials, including the Company's interpretation of the efficacy, safety and tolerability results from the Phase 2b study of TRV130 as compared to placebo and morphine and whether TRV130 ultimately will provide a better treatment option than existing opioids for patients with moderate to severe acute pain; the uncertainties inherent in conducting clinical trials; whether interim results from a clinical trial will be predictive of the final results of the trial or results of completed clinical trials will be indicative of the results of future trials, including with respect to whether the results of this Phase 2b study of TRV130 as well as prior clinical studies of this molecule will be consistent with the results obtained in any future Phase 3 studies; expectations for regulatory approvals; availability of funding sufficient for the company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; other matters that could affect the viability or commercial potential of the company's therapeutic candidates; the inherent uncertainties associated with intellectual property; and other factors discussed in the Risk Factors set forth in the company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission (SEC) and in other filings the company makes with the SEC from time to time. In addition, the forward-looking statements included in this press release represent the company's views only as of the date hereof. The company anticipates that subsequent events and developments may cause the company's views to change. However, while the company may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so, except as may be required by law.

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